REMARKS/ARGUMENTS

Claims 10, 12, and 19, 20, 22, 23, 25-32 are currently pending. Claims 21 and 24 have been cancelled. New claims 27, 31 and 32 correspond to prior claim 24, rewritten in independent form and removing the Markush format. New claims 28, 29, and 30 parallel claims 20, 10 and 12, and are supported throughout the specification.

The language in claim 19 is supported on page 5, lines 1-20 and throughout the specification.

No new matter is added by this specification.

I. *Specification:* The minor error in the brief description of the drawings has been corrected so that "3A to 2K" now properly reads "3A to 3K".

II. The cancellation of claim 21 renders any rejections thereof moot.

Applicants traverse this rejection.

III. *Claims 10, 12, 19-23, 25 and 26 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.*

Applicants respectfully traverse this rejection.

Figure 3 of the present specification provides an alignment between human utrophin and human dystrophin, with the repeats and hinge regions marked with respect to the utrophin protein above the sequence [SEQ ID NO:3]. Thus, the written description requirement is met.

Contrary to the examiner's comments regarding the hinge regions of utrophin, it was well-established as of the priority of the present application that utrophin contains four hinge regions. For example, Tinsley et al, US 6,518,413, relied upon by the examiner, provides in its Figure 4, a cartoon illustrating the N-terminus, C-terminus, and FOUR hinge regions (H1,

H2, H3 and H4). It is not necessary for applicants to re-teach to those of skill in the art what they already know.

The claims have been amended for purposes of clarity only. Support for this language is provided in the specification, *e.g.,* page 4, lines 21 - 30. No new matter is added by this amendment. The term microutrophin is provided with sufficient structure and function that it would be clear to one of skill in the art they were in the possession of the claimed invention as of the priority date.

Reconsideration and withdrawal of the invention is requested.

IV. *Claims 19, 21-23, 25 and 26 are rejected under 35 USC 102(a & e) as being anticipated by Tinsley et al, US 6,518,413.*

Applicant respectfully traverses this rejection.

Tinsley describes a utrophin "mini-gene" that encodes for a 2008 amino acid protein which contains both intact N-terminal and C-terminal amino acid domains of the utrophin protein, and all four hinge regions, H1, H2, H3 and H4 (see, Figure 4). In contrast, the microutrophin of the invention contains neither hinge region 3, repeats 18-21, nor the C-terminal-most 268 amino acids of utrophin.

Reconsideration and withdrawal of the rejection is requested.

V. *Claims 10, 12 and 20 are rejected under 35 USC 102(a & e) as anticipated by, or, in the alternative, under 35 USC 103(a) as obvious over Tinsley et al, US 6,518,413.*

Applicants respectfully traverses this rejection.

Tinsley describes a utrophin "mini-gene" that encodes for a 2008 amino acid protein which contains intact N-terminal and C-terminal amino acid domains of the utrophin protein. In contrast, the microutrophin of the invention is significantly smaller. Notably, and does not contain the H3-R21 region; nor does it require the 268 C-terminal amino acids of utrophin. Thus, Tinsley does not teach the invention.

The present inventors have recognized in the Tinsley construct several potential and previously unrecognized problems. The present invention offers solutions to these problems.

Tinsley's "mini-gene" is modelled on a natural mutation identified in a mild Becker muscular dystrophy patient, which retains the N-terminal and C-terminal portions of the utrophin, in which "all" of the repeat domains but none of the hinge regions may be removed. There is no recognition in Tinsley of the criticality of the triple helices and conformation in their utrophin "mini-gene". Thus, there can be no suggestion that some of these repeat domains *must* be retained, while the N-terminal region and/or C-terminus may contain deletions.

Tinsley does not teach or suggest adeno-associated virus vectors, which have significantly different properties from the adenoviruses and retroviruses suggested by Tinsley. Since there is no recognition in Tinsley of any problems associated with the use of these "vaccine" vectors, there can be no suggestion that it would be desirable to select another type of vector.

Further, while Tinsley alludes to potential immune problems due to recognition of their mini-gene as being "dystrophin-like" by a subject who has no native dystrophin, Tinsley address the problem by creating a chimeric human/murine or human/rat utrophin and defining it as "utrophin-like". This approach is wholly inapposite to the approach taken by the present invention.

For these reasons, Applicants fail to suggest the present invention.

Reconsideration and withdrawal of the rejection is requested.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to Howson & Howson's Deposit Account, Number 08-3040.

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